UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JONATHAN S. STAMLER, LIMIN LIU, ALFRED HAUSLADEN and RAPHAEL NUDELMAN

Appeal No. 2006-1565
Application No. 09/757,610

HEARD: June 8, 2006

Before SCHEINER, MILLS and GREEN, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of treating a patient suffering from a condition involving pathologically proliferating cells. The examiner has rejected the claims as lacking enablement. We have jurisdiction under 35 U.S.C. § 134. We will reverse this rejection.

Background

Glutathione-dependent formaldehyde dehydrogenase (GS-FDH), found in "a variety of bacteria, yeasts, plants and animals" (Specification, page 4), "oxidizes S-hydroxymethylglutathione and also provides NADH-dependent S-nitrosoglutathione reductase activity" (id.). According to appellants, GS-FDH "functions in vivo to metabolize

S-nitrosoglutathione and protein S-nitrosothiols to modulate [nitrosative stress], by controlling the intracellular levels of low mass NO [(nitric oxide)] donor compounds and preventing protein nitrosylation from reaching toxic levels" (id., pages 2-3). "[N]itrosative stress" refers to "an impetus for NO or NO_2 [(nitrogen dioxide)] group attachment to proteins, nucleic acids or other biological molecules" (id., page 1).

According to appellants, "where glutathione-dependent formaldehyde dehydrogenase is expressed to protect [pathologically proliferating cells] from nitrosative stress" (id., page 19), "administering . . . a therapeutically effective amount of an inhibitor of glutathione-dependent formaldehyde dehydrogenase" (id.) "selectively impos[es] nitrosative stress to inhibit proliferation of pathologically proliferating cells" (id., page 22).

The Claims

Claims 8-14, the only claims remaining in the application, stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. Claims 8-11 and 13 are representative of the subject matter on appeal and read as follows:

8. A method for treating a patient afflicted with pathologically proliferating cells, said method comprising administering to said patient a therapeutically effective amount of an inhibitor of glutathione-dependent formaldehyde dehydrogenase.

9. The method of Claim 8 where the pathologically proliferating cells comprise pathologic bacteria or fungus and the patient is afflicted with a bacterial or fungal infection which is mediated or caused by the pathologic bacteria or fungus and the administering kills the pathologic bacteria or fungus or reduces the rate of proliferation of the pathologic bacteria or fungus by at least 10%.

10. The method of Claim 8 where the pathologically proliferating cells are pathologically proliferating mammalian cells and the administering kills the pathologically proliferating mammalian cells or reduces the rate of proliferation of the pathologically proliferating cells by at least 10%.

11. The method of Claim 10 wherein the pathologically proliferating mammalian cells are cancer cells.

13. The method of Claim 10 wherein the pathologically proliferating cells are those causing restenosis.

Discussion

In its broadest aspect, the present invention is directed to a method of treating patients suffering from conditions involving various kinds of pathologically proliferating cells, wherein treatment comprises administering a therapeutically effective amount of an inhibitor of glutathione-dependent formaldehyde dehydrogenase in an amount effective to kill or reduce the proliferation rate of the pathologically proliferating cells.

Claims 8-14 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification "does not reasonably provide enablement for killing or reducing the growth of pathologically proliferating mammalian cells in vivo" (Answer, page 3). According to the examiner, "[t]he specification fails to provide information that would allow the skilled artisan to practice the invention without undue experimentation" (id.), because "[t]herapies involving cancer and pathologically proliferating cells are unpredictable" (id. page 4), and "[t]he working examples lack sufficient data to understand if the clinical results will invariably occur" (id.).

While "enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation,' [the fact] [t]hat some experimentation may be required is not fatal; the issue is whether the amount of experimentation is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (citation omitted, emphasis original). Whether the amount of experimentation required is undue is determined by reference to the well-known Wands factors. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 2223, 169 USPQ 367, 369 (CCPA 1971) (emphasis original). "[I]t is incumbent upon the Patent Office . . . to explain why it doubts the truth and accuracy of any statement in the supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. In other words, "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by [the] claim[s] is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Thus, the issue here is not whether appellants have established that the disclosure is enabling for the scope of the claims; the issue is whether the PTO has met its "initial burden of setting forth a reasonable explanation as to why" it is not.

On this record, we find that the examiner has not adequately explained why practicing the full scope of the claims would have required undue experimentation. Initially we note that the enablement rejection does not begin to address those claims

directed to treating restenosis (claim 13), or treating bacterial or fungal infections (claim 9), by inhibiting GS-FDH.

With respect to the remaining claims, some of which are limited to killing cancer cells or reducing their rate of proliferation by inhibiting GS-FDH, the examiner cites Dermer[1] as evidence that "'petri dish cancer is really a poor representation of malignancy, with characteristics profoundly different from the human disease'" (Answer, page 4, and Dermer, column 1). The examiner's implication, of course, is that the in vitro examples in the specification would not be predictive of in vivo results in a cancer patient. Nevertheless, we agree with appellants that "Dermer is not specific enough to the facts of the instant case" (Reply Brief, page 4) to cast doubt on any assertions in the specification as to the scope of enablement.

According to the specification, GS-FDH is a highly conserved enzyme that protects many types of cells (bacterial, fungal, plant, mammalian) from nitrosative stress (Specification, pages 4 and 33). The examples in the specification appear to demonstrate that inhibition or reduction of GS-FDH activity in cells of various types (not just malignant cells) makes the cells more susceptible to the lethal or detrimental effects of nitrosative stress. See e.g., the in vitro examples on pages 33-36 of the specification. The examiner has not begun to explain the relevance of Dermer's general comments regarding "long-term cell cultures [that] began their careers as stand-ins for real cancer based only investigator faith" (id.) to any of the examples in the specification.

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[1] G.B. Dermer, "Another Anniversary for the War on Cancer," Bio/Technology, Vol. 12, p. 320 (March 12, 1994).

In our view, the reasons and evidence cited in support of the examiner's rejection do not provide a reasonable basis to question the adequacy of the disclosure provided for the claimed invention. Accordingly, the rejection of claims 8-14 under 35 U.S.C. § 112, first paragraph, for lack of enablement is reversed.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
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Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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Lora M. Green) INTERFERENCES
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